K124037



# 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

**1. Submitted by :** September /02 / 2013

Kyu Lee / Overseas sales manager
**Jung Rim Medical Industrial Co., Ltd.**
#593-81, Sagok-Ri, Iwol-Myeon, Jincheon-Gun, Chungbuk, 365-820, Korea
Phone : +82 2 404 7986 Fax : + 82 2 404 7989

**2. Device Name :**

Trade Name : Jung Rim single use hypodermic Syringe with Needle

◈ Piston syringe

- Classification : Class II
- Classification Name : Syringe, Piston
- Product Code : FMF
- Regulation Number : 21 CFR 880.5860
- Review Panel : General Hospital

SEP 1 2 2013

◈ Hypodermic single lumen needle

- Classification : Class II
- Classification Name : Hypodermic single lumen needle
- Product Code : FMI
- Regulation Number : 21 CFR 880.5870
- Review Panel : General Hospital

**3. Predicate Device :**

**a) K number : K113091**

- Manufacturer : Jiangyin Caina Technology Co., Ltd.

1) Proposed Device Name: Syringes with or without needles

Classification: Class II

Product Code: FMF

Regulation Number: 21 CFR **880.5860**

2) Proposed Device Name: Needles

Classification: Class II

Product Code: FMI

Regulation Numiber: 21 CFR **880.5570**

**b) K number : K072739**

- Manufacturer : ShanDong WeiGao Group Medical Polymer Products Co., LTD

1) Proposed Device Name: Sterile Hypodermic Syringe for single use, with/without needle (1,2,3,5,10,20,30,50,100(ml))

Classification: Class II

Product Code: FMF

Regulation Number: 21 CFR **880.5860**

2) Proposed Device Name: Sterile Hypodermic Needle for single use (16G,18G,19G,20G,21G,22G,23G,24G,25G,26G,27G,29G)

Classification: Class II

Product Code: FMI

Regulation Numiber: 21 CFR **880.5570**

**4. Device Description :**

The Single use hypodermic Syringe with Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. The product consists of a Barrel, Piston, Gasket, Needle Needle cap.

The Single use hypodermic Syringe with Needle are offered various sizes (Luer slip (1,3,5,10,20,30,50 (ml)), and Needle size (16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G)

Proposed syringes will be provided along with a proposed needle in one single package. The combinations of sizes are various upon the request of the users.

These are sterile (Eo gas sterilization). The devices are disposable, single use devices.

**5. Intended For Use :**

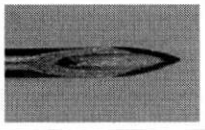
1) The single us hypodermic syringe
The Single use hypodermic Syringe with needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

2) The Hypodermic needle
The Sterile hypodermic needle for single use is intended for use with syringes for general purpose fluid injection/aspiration

Proposed syringes will be provided along with a proposed needle in one single package. The combinations of sizes are various upon the request of the users.

**6. Technological Characteristics :**

The Single use hypodermic Syringe with needle and the predicate device have the identical technological characteristics and perform equivalently.

| **Device Name** | | **Subject Device** | **Predicate Device #1** | **Predicate Device #2** |
|---|---|---|---|---|
| Manufacturer | | Jung Rim Medical Industrial Co., Ltd. | Jiangyin Caina Technology Co., Ltd. | ShanDong WeiGao Group Medical Polymer Products Co., LTD |
| 510(k) Number | | NEW | K113091 | K072739 |
| Syringe | Classifi-cation | Class II | Class II | Class II |
| | Product code | FMF | FMF | FMF |
| | Regulation Number | 21 CFR 880.5860 | 21 CFR 880.5860 | 21 CFR 880.5860 |
| Needle | Classifi-cation | Class II | Class II | Class II |
| | Product code | FMI | FMI | FMI |
| | Regulation Number | 21 CFR 880.5870 | 21 CFR 880.5870 | 21 CFR 880.5870 |
| Intended for use | Syringe | The Single use hypodermic Syringe with needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. | Syringes with or without needle are intended to inject fluids into or withdraw fluids from the body. | The sterile Hypodermic syringe for single Use With/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. |
| | Needles | The Sterile hypodermic needle for single use is intended for use with syringes for general purpose fluid injection/aspiration. | Needles are intended to be used with a legally marketed syringe intend to inject fluids into or withdraw fluids from the body. | The Sterile Hypodermic needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration. |
| Syringe | Syringe type | Piston syringe | Piston syringe | Piston syringe |
| | Tip type | Luer slip | Luer slip and Luer lock | Luer slip and Luer lock |
| | Volume | 1ml 3ml 5ml 10ml 20ml 30ml 50ml | 1,2,3,5,10,20,30,50 (ml) | 1,2,3,5,10,20,30,50,100(ml) |
| Needle | Gauge | 16G, 17G, 18G, 19G, 20G, 21G, 22G,23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G | 16G,18G,19G,20G, 21G,22G,23G, 24G,25G,26G,27G,29G | 16G,18G,19G,20G, 21G,22G,23G, 24G,25G,26G,27G,29G |
| | Tip configuration |  | same | same |
| | Hub color | According to ISO 6009 | According to ISO 6009 | According to ISO 6009 |

| Device Name | | | Subject Device | Predicate Device #1 | Predicate Device #2 |
|---|---|---|---|---|---|
| Manufacturer | | | Jung Rim Medical Industrial Co., Ltd. | Jiangyin Caina Technology Co., Ltd. | ShanDong WeiGao Group Medical Polymer Products Co., LTD |
| 510(k) Number | | | NEW | K113091 | K072739 |
| Materials | Syringe | Barrel | lubricated polypropylene | lubricated polypropylene | lubricated polypropylene |
| | | Plunger | polypropylene | polypropylene | polypropylene |
| | | Gasket | Styrene ethylene / Butylene copolyme | Resin stopper | Resin stopper |
| | Needle | Tubing | lubricated stainless (STS304) | lubricated stainless (STS304) | lubricated stainless (STS304) |
| | | Hub | polypropylene | polypropylene | polypropylene |
| | | Sheath | polypropylene | polypropylene | polypropylene |
| | | Bonding | Epoxy bond | Epoxy bond | Epoxy bond |
| | | Lubricant | Dimethylpolysiloxane | Dimethylpolysiloxane | Dimethylpolysiloxane |
| Principle of operation | | | **1.** Check that the syringe package is undamaged and unopened. Discard if damaged or opened.<br>**2.** Peel open the end of the package and remove the syringe.<br>**3.** Wipe the top of the vial with alcohol and allow it to air dry.<br>**4.** Remove the shield from the needle. Do not move the plunger, and do not try to inject air into the vial, as this will disable the syringe.<br>**5.** Pick up the vial and invert it. Insert needle into the vial.<br>**6.** Keep the needle tip in the fluid at all times. Do not draw air into the syringe. It may lead to an inaccurate dose. To fill the syringe, slowly pull the plunger To remove air bubbles, remove the needle from the vial.<br>**7.** Holding the syringe upright, tap the barrel to bring the bubbles towards the tip of the syringe.<br>**8.** Then carefully push the plunger to the dose mark, thus expelling the air bubble.<br>**9.** Administer the injection<br>**10.** Depress the plunger completely to deliver the dose. | Same | Same |
| Biocompatibility | | | ISO10993-1 | ISO10993-1 | ISO10993-1 |
| Sterilization | | | Ethylene oxide gas (SAL $10^{-6}$) | Ethylene oxide gas (SAL $10^{-6}$) | Ethylene oxide gas (SAL $10^{-6}$) |

**Performance Testing**

The Single use hypodermic Syringe with needle have been designed and successfully tested to meet the applicable requirements outlined in ISO7886-1, ISO7864, ISO9626, ISO6009 and ISO594-1.

**Biocompatibility Testing**

The material of the Single use hypodermic Syringe with needle have successfully passed testing as outlined in ISO10993-1 for devices categorized as External communicating devices, Limited exposure.

**Sterilization and Shelf-life Testing**

Sterilization of the Single use hypodermic Syringe with needle has been validated using the half-cycle method as outlined in ISO11135.

The maximum levels of residues of ethylene oxide and ethylene chlorohydrins will not exceed the limits presented in ISO10993-7. Shelf-life testing supports a shelf-life of 5-years after sterilization

**Clinical Data**

No prospective clinical trials were conducted in support of this Traditional 510(k)

**8. Conclusion**

Based on the information provided in this premarket notification of **Jung Rim Medical Industrial Co., Ltd.** Concludes that The Sterile Hypodermic Syringe for Single Use with needle is substantially equivalent to predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 12, 2013

Jung Rim Medical Industrial Company Limited
C/O Mr. Kyu Lee
593-81, Sagok-Ri, Iwol-Myeon, Jincheon-Gun
Chungbuk 365-820 Korea

Re: K124037
Trade/Device Name: Jung Rim Single Use Hypodermic Syringe with Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, FMI
Dated: August 14, 2013
Received: August 15, 2013

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indication for use Statement

**510(k) Number ( If known ) :** K124037

**Device Name :** Jung Rim single use hypodermic syringe with Needle

**Indication for use :**

Jung Rim single use hypodermic syringe with Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

**Prescription Use** X AND/OR **Over-The-Counter** _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

)ivision Sign-Off)
:vision of Anesthesiology, General Hospital
fection Control, Dental Devices

Richard C. Chapman
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